

Serial No. 10/791,895  
Amendment dated August 15, 2008  
In Reply of Office Action dated April 15, 2008

REMARKS

The Office Action, dated April 15, 2008, has been received and its contents carefully noted.

In view of the foregoing Amendments, and following representations, reconsideration and allowance are respectfully requested.

Examiner Brandon Lee Jackson and Primary Examiner Michael Brown are thanked for the courtesies extended undersigned counsel during the personal interview of July 23, 2008.

During that July 23, 2008, interview, the undersigned explained the novel and non-obvious features of Applicant's inventive esophageal airway guide. Undersigned counsel further pointed out that U.S. Patent No. 3,508,554 to Sheridan (hereinafter "Sheridan") disclosed only one (1) function, not a variety of functions as argued by the Examiner. The undersigned pointed out that Sheridan simply stated in the field of the invention that a variety of tubes were known; e.g., for a variety of needs. The plain language interpretation of that statement meant that there were lots of different tubes having lots of different functions; that statement could not reasonably be understood to mean that there are a variety of tubes, each of which had a variety of functions. Further, the undersigned

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pointed out that the Sheridan device was not flippable; indeed, the Sheridan device was not configured for such. Further, the undersigned explained that, contrary to the Examiner's reasoning, Applicant's particularly claimed specificity of hardnesses (SHORE hardnesses) did indeed have a particular function and the criticality thereof had been set forth in the specification, as the particular durometer hardnesses related to whether or not the user (i.e. the physician) wanted to insert Applicant's guide into a patient's lungs or into a patient's stomach. That is a critical feature because in the real world if a physician inserts a guide intended to go into a patient's stomach with a prior art device and the guide goes unintentionally into the patient's lungs, then the patient's lung can be perforated and the patient can be injured, for example. Still further, the undersigned pointed out that, the Examiner's reasoning to the contrary, the Sheridan device modified in view of the Field device could not be bent at a forty degree angle because it is only Applicant's device which is intended to be used by flipping Applicant's device around. Each one of Sheridan and Field are intended to be used in only one manner.

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Still further, in that July 23, 2008, personal interview, Examiner Jackson agreed to discuss with at least one or two other Patent Examiners, in addition to Primary Examiner Michael Brown, whether or not Examiner Jackson's reading of Sheridan as suggesting that there are known devices each of which have multiple functions is a reasonable reading of Sheridan's Field of the Invention. Specifically, Examiner Jackson said he would talk to a TQAS (Technical Quality Assistant Specialist) within his art unit/group in this regard.

No final agreement as to patentability was reached, and the focus on the prior art was on the Sheridan and Field references.

As to the Office Action in detail, please note the following:

As to the rejection of the claims under 35 USC 103 as being unobvious over Sheridan modified in view of Field, such is respectfully traversed.

First, it is submitted that the Examiner has failed to make a prima facie case of obviousness under the present standards dictated by the Examination Guidelines of the MPEP and the Courts.

Second, assuming, for the sake of argument, that it would have been obvious to a person having ordinary skill in the art

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at the time of Applicant's invention, to modify the Sheridan medical-surgical tube with the Field introducers and assemblies, absent any clear motivation therefor, Applicant's invention still would not have resulted.

For example, the proposed combination would have lacked at least Applicant's nonobvious "dual function flippable insert" which is particularly configured and has particularly claimed hardnesses so that the single flippable insert can be inserted into a patient's trachea for positioning both extraglottic and subglottic tubes without injury to the patient's soft tissues.

Rather, the Sheridan device is intended to be inserted in only one (1) way. Sheridan discloses a "proximal end 8" (Fig. 1) and a "distal end 6" (Fig. 2). Sheridan clearly describes that distal end 6 is the end 6 which is intended to be inserted into the patient's body. See Figs. 1 and 2, Claim 1, and column 4, lines 62-74 of Sheridan, for example. In that passage Sheridan clearly states that tubular member 4 has "a distal end 6 and a proximal end 8". Further, Claim 1 states that "said distal end being adapted for the insertion of the catheter into the body of a patient". See Claim 1, lines 4-6. Still further, Sheridan disclosed that "Markings 10 are provided on the tubes to designate the distance from the distal end to aid the

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physician or surgeon in use of the tube [... these distance markings ...] will generally designate 12, 13.5, and 15 cm. distance from the distal end". Thus, it would have been understood to one in the art that those distance markings would show the physician how far into the patient's body distal end 6 had been inserted. In that manner, as known in the art, the user instantly sees that he or she has already inserted the tube "15 cm". Thus, the user knows when to stop inserting the tube to avoid inserting the tube so far that a part of the lung, for example, is unintentionally perforated by distal end 6. A person having ordinary skill in the art would understand that it is distal end 6, and only distal end 6, which is intended to be inserted into the patient because the user is only interested in knowing how far into the patient he or she has stuck the endotracheal tube 2 of Sheridan. The Examiner's reasoning to the contrary, it is respectfully submitted that no person having ordinary skill in the art would have thought, expected, or understood Sheridan as having taught that proximal end 8 would ever be inserted into a patient's body.

Still further, as explained in the personal interview of July 23, 2008 summarized above, it is respectfully submitted

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that no person having ordinary skill in the art could have reasonably read Sheridan's description under Field of the Invention that there are multiple medical tubes known which have multiple functions in one tube, as reasoned by the Examiner. Sheridan clearly states in column 1, lines 33--42, that "A wide variety of medico-surgical tubes of the disposable plastic variety are required to meet modern medical and surgical needs, e.g., catheters, feeding tubes, [...] sump drain tubes, post-surgical drainage tubes, suction catheters and the like. The present invention concerns improvements which may be applied to any of these types of medical-surgical tubes." Sheridan clearly meant, in applicant's opinion, that Sheridan's surgical tube having a frosted surface could be applied to any one of those variety of tubes. Sheridan would not have been understood by a person having ordinary skill in the art, nor anyone giving that statement a standard plain language reading of that statement, that Sheridan meant that there are lots of tubes which are multi-function tubes. Sheridan is stating that there are lots of different tubes for use in lots of different functions where a tube is needed. His frosted tube is meant to be usable in any of those different situations.

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It is respectfully submitted that only a strained reading of that passage with benefit of hindsight, at best, using Applicant's claimed invention as a guide, would have yielded an understanding that Sheridan meant to say that a wide variety of medico-surgical tubes are required to meet modern medical and surgical needs, and that that wide variety of tubes includes tubes having multiple functions; as opposed to a standard plain language reading that there are a lot of different tubes which are used to perform a lot of different functions. Nowhere in this statement, nor anywhere else in Sheridan, is a statement which can fairly be construed to mean that there are a variety of surgical tubes, each of which has a variety of functions.

The Examiner is respectfully requested to reconsider his reading of Sheridan, and withdraw his assertion that "Sheridan discloses an esophageal device comprising a slender tube/insert (2) that has multiple functions." Col. 1, line 33-42 of the Office Action. That synopsis in Examiner Jackson's second sentence of his Section 103 Rejection is respectfully submitted to be a conclusory statement for which no showing has been made. In other words, a conclusion which would not have been understood by or obvious to a person having ordinary skill in the art from reading Sheridan. Applicant can find no support

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for that statement, which inherently requires a conclusion to be drawn on the part of the reader.

Still further, the Examiner has asserted in the sentence linking pages 3 and 4 of the 103 Rejection that "Applicant has not disclosed that this specificity [i.e. of the lengths and hardnesses claimed by the Applicant] implies any "particular criticality or useful advantage".

Applicant respectfully disagrees with the Examiner's conclusion, as Applicant has set forth in the Specification, as filed, with particularity, that the hardnesses and the length (i.e. percentages of the length) over which Applicant's hardnesses extend relate directly to the function of, and to the structure of, Applicant's inventive esophageal airway management device by having a flippable insert. Thanks to the claimed differences in hardness, which have not been claimed as relative terms such as --harder-- or --softer--, but rather have been claimed with specific "selected hardness of between about 50 SHORE A to about 90 SHORE D", for example. These hardnesses relate to which end of Applicant's flippable insert is being used, and particularly claimed to protect the (soft) tissue of



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the patient, in use, indeed, in use for being inserted into the different pathways in the patient's esophagus.

Still further, applicant traverses the Examiner's assertion at the top of page 5 that "Moreover, either side of the Sheridan/Field insert could be bent at a 40 degree angle and inserted into the patient first." That statement is respectfully traversed given that it is impermissible hindsight reasoning based on Applicant's inventive flippable insert having two ends (proximal and distal), and each of which ends, not one or the other as in the prior art, is particularly configured for insertion into the patient first.

It was already set out above, how Sheridan was insertable into a patient only by inserting Sheridan's distal end 6 first. That distal end 6 was for insertion into the patient. There is no disclosure nor suggestion that the proximal end 8 of Sheridan would have been inserted first into a patient, not only because Sheridan has characterized distal end 6 as being "adapted for the insertion of the catheter into the body of a patient" (claim 1), but because Sheridan had markings 10 which referenced distances from distal end 6.

Field, likewise, clearly showed and described what Field described as "patient end 11 of the tube 1". See, for example,

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Field's unequivocal statement in Column 2, lines 28-31 "in use, the patient end 11 of the tube 1 is inserted through the patient's mouth so that it extends through the vocal folds and is located in the trachea, with the machine end 14 of the tube projecting from the patient's mouth". See related Figs. 1-3, which clearly show each step and patient end 11 not only going into, but being inside of, the patient.

In sum, the Examiner is respectfully requested to reconsider his position as regards the previously amended claims, none of which have been amended by this response, withdraw the rejection, and pass the Application on for allowance. Applicant submits that the Application is now clearly in condition for allowance.

The Application is submitted to be in condition for allowance, with Claims 1-6, 10-13, and 22-24.

Claims 3, 5, 6, and 13 have been previously withdrawn from consideration.

Claims 1, 2, 4, 10-12, and 22-24, have been rejected.

Claim 1 is in Independent form.

Examiner Brandon Lee Jackson is requested to charge \$60.00 (small entity) for a one-month extension of time to our Deposit Account No. 19-2105. It is believed that no fee additional fee

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is due for this submission. However, should that determination be incorrect, Examiner Brandon Lee Jackson is hereby authorized to charge any deficiencies to our Deposit Account No. 19-2105 and notify undersigned counsel in due course.

Should any outstanding formal matters or other issues remain, Examiner Jackson is requested to telephone Terrence Brown to resolve such.

Respectfully submitted,

Date: August 15, 2008

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